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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,250	09/15/2000	David G. Matsuura	18608-001910	3797
7590 04/21/2004		EXAMINER		
Jonathan Spangler			DAVIS, DANIEL J	
Nvasive, Inc 10065 Old Grove Road			ART UNIT	PAPER NUMBER
San Diego, CA 92131			3731	16
			DATE MAILED: 04/21/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

,	Application No.	Applicant(s)				
Office Action Summary	09/663,250	MATSUURA ET AL.				
Onice Action Summary	Examiner	Art Unit				
The MAILING DATE of this communication	D. Jacob Davis	3731				
Period for Reply		iai die con coponaciice dadress				
A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 Cl after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, If NO period for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	ON. FR 1.136(a). In no event, however, may a on. a reply within the statutory minimum of thi period will apply and will expire SIX (6) MO statute, cause the application to become A	reply be timely filed rty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	<u>22 January 2004</u> .					
2a) ☐ This action is FINAL . 2b) ☑	This action is FINAL . 2b)⊠ This action is non-final.					
,						
closed in accordance with the practice un	der <i>Ex parte Quayle</i> , 1935 C.I	J. 11, 453 O.G. 213.				
Disposition of Claims						
 4a) Of the above claim(s) is/are wit 5) ⊠ Claim(s) 10 and 11 is/are allowed. 6) ⊠ Claim(s) 1-3,5,6,8,14 and 15 is/are rejected. 7) ⊠ Claim(s) 4,7,9,12,13 is/are objected to. 	☐ Claim(s) <u>1-3,5,6,8,14 and 15</u> is/are rejected.					
Application Papers						
9) The specification is objected to by the Exa 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the or 11) The oath or declaration is objected to by the] accepted or b) □ objected to o the drawing(s) be held in abeya orrection is required if the drawing	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for fo a) All b) Some * c) None of: 1. Certified copies of the priority docur 2. Certified copies of the priority docur 3. Copies of the certified copies of the application from the International B * See the attached detailed Office action for	ments have been received. ments have been received in a priority documents have been ureau (PCT Rule 17.2(a)).	Application No received in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)		Summary (PTO-413) (s)/Mail Date				
 Notice of Draftsperson's Patent Drawing Review (PTO-94 Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date 	-/	Informal Patent Application (PTO-152)				

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 8, 14 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by Forber et al. (US 5,733,294). Forber discloses a genererally cylindrical shaped mesh 22 (element 228 is the wire while element 22 is generally the mesh) in Fig. 10. The mesh as illustrated is expanded against the sides of the wall of the aneurysm hole. The "connection" 25 is moved (by interior forces) into an interior portion of the mesh. The proximal end of the mesh is "moved in a distal direction."

Regarding claim 3, a push rod is used to advance the device out of the catheter, just like the embodiment of Figs. 4-5e (col. 6, lines 18-20). For claim 5, what is traditionally considered the distal end of the hole is the proximal end of the hole. The device creates an ingress and egress prevention element once a clot has been formed. Regarding claims 14 and 15, the internal spring forces of the device cause the mesh to both "pull" and "push" the mesh as it expands.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Leschinsky (US 5,904,713). Leschinsky discloses a method of "sealing" a hole in a body

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comprising introducing a cylindrically shaped mesh 8 and 9 into a hole and pulling the distal end 8 of the mesh through an interior portion of itself (proximal end 9). The distal end 8 is simply inverted within the distal end 9. The hole is "sealed" in that the device is constricted about the perimeter of the passage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(c) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 12 and 13 are rejected under 35 U.S.C. 103(c) as being unpatentable over Forber et al. (US 5,733,294) in view of Ken (US 6,293,960). Forber does not disclose that the catheter or "tubular insert" 40 is inserted into the hole of the aneurysm. Nevertheless, Ken discloses a catheter inserted into an aneurysm to implant a device within the aneurysm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the Forber catheter within an aneurysm as taught by Ken to accurately place the implant and ensure that the device does not expand prematurely preventing the device from entering the aneurysm. A push rod is used to advance the device out of the catheter. Ken does disclose removing the catheter to expel the device (col. 5, lines 48-53) and pushing the inserter tool 42.

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Allowable Subject Matter

Claims 10 and 11 are allowed. The prior art fails to disclose or suggest all of the limitations of the claims including the device used within a bony structure. Claims 4, 7 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to disclose or suggest all of the limitations of the claims including, "the proximal ["distal" in claim 7] end [is] advanced distally ["proximally" in claim 7] past the proximal end."

Response to Arguments

Applicant's arguments filed January 12, 2004 with respect to claims 1-14 are moot in view of the new grounds of rejection. With respect to the rejection under U.S.C. 102 over Leschinsky, the patent describes one of the legs as "substantially tubular." If one of the legs may be considered substantially tubular, then the device "comprises a generally cylindrical shaped mesh." In the alternative, the device as a whole, even though it is formed in two sections, appears to be generally cylindrical.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD April 6, 2004

MICHAEL J. MILANO SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700